APPEAL BRIEF

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TABLE OF CONTENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kazuhiko Inoue, et al.	**Examiner:**	Gregory Listvoyb
Serial No.:	10/518,859	**Art Unit:**	1796
Filed:	December 17, 2004	**Docket:**	18493
For	BIODEGRADABLE RESIN, BIODEGRADABLE RESIN COMPOSITION, BIODEGRADABLE MOLDED OBJECT, AND PROCESS FOR PRODUCING BIODEGREDABLE RESIN	**Dated:**	May 12, 2010

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Commissioner for Patents
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APPEAL BRIEF (Corrected)

Sir:

Pursuant to 35 U.S.C. § 134 and 37 C.F.R. § 41.37, entry of this Appeal Brief in support of the Notice of Appeal filed January 19, 2010 in the above-identified matter is respectfully requested. This paper is submitted as a brief setting forth the authorities and arguments upon which Appellants rely in support of the appeal from the Final Rejection of Claims 43, 44, 51-54 and 131 in the above-identified patent application on August 18, 2009. The rejection of Claims 43, 44, 51-54 and 131 currently remains.

I. REAL PARTY OF INTEREST

The real party in interest is NEC Corporation, assignee of 100% interest of the above-referenced patent application.

II. RELATED APPEALS AND INTERFERENCE

There are no other appeals or interferences known to Appellants, Appellants' legal representative or Assignee, which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 43, 44, 51-54 and 131 are pending in the Application. Claims 50, 67-70 and 134 are allowed. Claims 43, 44, 51-54 and 131 are being presented on appeal, and are set forth fully in the attached Appendix.

Claims 43, 44 and 51-54 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chen et al. (U.S. Patent No. 6,018,033; hereinafter "Chen") in view of Ruben (U.S. Patent No. 6,146,655; hereinafter "Ruben") and further view of Helmus et al. (U.S. Publication No. 2004/0093080; hereinafter "Helmus").

Claim 131 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Chen in view of Ruben, Helmus and further view of Wiessler et al. (U.S. Patent No. 6,958,395; hereinafter "Wiessler").

Appellants respectfully appeal the rejection of claims 43, 44, 51-54 and 131 as being unpatentable over Chen in view of Ruben, Helmus and Wiessler, which is the sole issue in this Appeal.

IV. STATUS OF AMENDMENTS

Appellants filed an Amendment under 37 C.F.R. §1.116 on November 18, 2009. Appellants amended no claims in the Amendment.

Appellants timely filed a Notice of Appeal on January 19, 2010. Therefore, the claims are pending as set forth in the Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 43, 44, 51-54 and 131 are being presented on appeal, and are set forth fully in the attached Appendix.

Appellants mention that reference numbers, figure numbers and references to passages in the Specification used in this section and other sections of the Appeal Brief are provided merely for the benefit of the Board and for meeting the requirements set forth in 37 C.F.R. § 41.37(c)(v) and are not meant to limit the scope of the claimed invention in any manner.

INDEPENDENT CLAIM 43

The invention of claim 43 is directed to a biodegradable moldable resin. The resin (e.g. see Application at page 9 lines 20-22) has a Diels-Alder type functional group (e.g. see Application at page 15 lines 12-20) having a thermo-reversible cross-linked structure (e.g. see Application at page 15 lines 14-25) which is covalently bonded by cooling and cleaved by heating (e.g. see Application at page 15, line 11 to page 16, line 25), wherein said functional group (e.g. see Application at page 15 lines 12-20) forms said thermo-reversible cross-linked structure (e.g. see Application at page 15 lines 14-25) which is covalently bonded at a temperature for use as a molded article and cleaved at temperatures over 120°C (e.g. see Application at page 25, lines 17-22) and equal to or lower than the molding temperature (e.g. see Application at page 25, line 17 to page 26, line 1), and wherein said Diels-Alder type functional

group (e.g. see Application at page 15 lines 12-20) forms the covalent bonds, wherein the biodegradable resin (e.g. see Application at page 9 lines 20-22) is selected from the group consisting of polylactic acid, modified body of the polylactic acid, polybutylene succinate and modified body of the polybutylene succinate (e.g. see Application at page 10, lines 5-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review by the Board of Patent Appeals and Interferences are whether independent claim 43 and dependent claims 44, 51-54, 131 are unpatentable over Chen in view of Ruben, Helmus and Wiessler under 35 U.S.C. §103(a).

VII. ARGUMENT

Rejection under 35 U.S.C. §103(a) as being unpatentable over Chen in view of Ruben and further in view of Helmus and Wiessler.

1. THE EXAMINER'S POSITION

a. Independent claim 43

In the Final Office Action mailed August 18, 2009, the Examiner rejected Claims 43, 44 and 51-54 under 35 U.S.C. §103(a) as being unpatentable over Chen in view of Ruben and Helmus.

a1)

The Examiner alleged, "Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120°C (Abstract, Column 6, line 35, Figure 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples III-1 and III-2 and Column 7, line 35)." (See Final Office Action on August 18, 2009 at page 2).

a2)

The Examiner alleged, "Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1). The advantage of Ruben is that the above gel can be molded in the shape of water-permeable porous envelope (see Abstract), which can be used in oral applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60). Therefore, it would have been obvious to a person of ordinary skills to use Chen's polysaccharides in moldable drug delivery compositions, since it allows increasing applicability of the material." (See Final Office Action on August 18, 2009 at page 3).

a3)

The Examiner alleged, "Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as Chen's one. Helmus teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130). Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116). It would have been obvious to a person of ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material are known material based on its suitability for its intended use." (See Final Office Action on August 18, 2009 at page 4).

b. Dependent claim 131

In the Final Office Action mailed August 18, 2009, the Examiner rejected Claim 131 under 35 U.S.C. §103(a) as being unpatentable over Chen in view of Ruben, Helmus and Wiessler.

b1)

The Examiner alleged, "Wiessler teaches biodegradable reversible system (see line 0008), based on polysaccharide (see line 0011) and cyclic or acyclic diene (see line 0006). Wiessler teaches that the above reagents produce a compound with well controlled structure and quantitative yield (see line 0008). Also, Wiessler discloses that the reaction can be performed at mild conditions (see line 0008). Therefore, it would have been obvious to a person of ordinary skills in the art to interchangeably use cyclic and acyclic dienes in Chen's composition, modified with Ruben, since these compounds are known material based on its suitability for its intended use." (See Final Office Action on August 18, 2009 at page 6).

2. APPELLANTS' POSITION

Appellants submit that the Examiner's position is unsound as a matter of fact and law. Thus, claims 43-44 and 51-54 are not unpatentable under 35 U.S.C.§103(a) over Chen in view of Ruben and Helmus, and claim 131 is not unpatentable under 35 U.S.C. §103(a) over Chen in view of Ruben, Helmus and Wiessler.

a. Independent claim 43

a1)

Chen discloses gels and foams derived from saccharides, which can be used in the controlled release of drugs (see column 1, lines 8-11).

Chen synthesizes saccharide monomers with an epoxy (meth)acrylate, a (meth)acrylohalide and an acyl halide, a (meth)acryloyl aminocarboxylate, a 2,4-dienyl carboxylate, an α-alkynyl carboxylate, an activated (meth)acrylate of a poly(alkylene oxide), and (meth)acryloisocyanates (see column 5, line 25 through column 8, line 11, formulas (I-VII), Figure 1A-G).

Chen polymerizes the saccharide monomers to prepare the gels or the foams by conventional methods such as mass polymerization, solution (or homogeneous) polymerization, suspension polymerization, emulsion polymerization, radiation polymerization (using γ-ray, electron beam or the like), or the like (see column 10, lines 14-19).

For example, Chen synthesizes the sucrose glycidyl acrylate (S-GA) monomers (see Example I-1), then polymerizes them by γ-irradiation or by chemical initiation, preparing the S-GA gels (see Example I-3) or fabricates the S-GA foams using acrylic acid as a blowing agent (see Example I-5).

Chen defines the swelling ratio, Q, an important parameter for the gels or the foams, as:

$$Q=(W_s - W_d)/W_d$$

where W_s and W_d are the weights of the gels and the dried gels; being immersed under water, the gels absorb water and swell; Chen measures the volume of water absorbed, calculates W_s and thus Q (see column 11, line 41 through column 12, line 12).

Chen compares the swelling properties of the S-GA foams and gels in Table 2; under the same swelling condition, the foams usually swell about 7-10 times larger than the gels; the foams contain numerous empty cells which are dispersed throughout the polymer matrix; when the foams swell in aqueous solution, not only the polymer chains expand with the uptake of water, as

in hydrogels, but also numerous empty cells expand to even larger sizes; this accounts for the much higher Q value of foams compared to hydrogels (see Table 2, column 14, lines 20-30).

To summarize, Chen teaches the saccharide derived polymers, foams and gels, which can absorb water and swell when immersed under water, and which can be applicable to a drug delivery system. The expansion of the polymer chains and of the cells in the foams and gels brings about the absorption and the swelling.

On the other hand, independent claim 43 recites,

A biodegradable moldable resin having a Diels-Alder type functional group having a thermo-reversible cross-linked structure which is covalently bonded by cooling and cleaved by heating,

wherein said functional group forms said thermo-reversible cross-linked structure which is covalently bonded at a temperature for use as a molded article and cleaved at temperatures over 120°C and equal to or lower than the molding temperature and wherein said Diels-Alder type functional group forms the covalent bonds,

wherein the biodegradable resin is selected from the group consisting of polylactic acid, modified body of the polylactic acid, polybutylene succinate and modified body of the polybutylene succinate.

The biodegradable moldable resin is made out of polylactic acid or polybutylene succinate, and has Diels-Alder type functional groups, which form thermally reversible cross-linked structures by covalent bond. The groups covalently bond at a temperature for use, e.g. lower than 100°C, and split at temperatures over 120°C and equal to or lower than the molding temperature, e.g. 280°C, making the resin with higher qualities of heat resistibility, moldability, recyclability and biodegradability.

Appellants note that the biodegradable moldable resin of the present invention as recited in independent claim 43, is prepared from polylactic acid or polybutylene succinate, whereas Chen's foams and gels are prepared from saccharide. When the backbone polymers are different, so are the chemistries. The Diels-Alder type functional groups of the present invention covalently bond at temperatures lower than 100°C and split at over 120°C, whereas Chen's foams and gels expand their polymer chains and cells when absorbing water. There is no chemical cleavage in this expansion. The present invention could replace durable plastics with biodegradable ones, whereas Chen's foams and gels only apply to drug delivery systems. The applicable technical fields are different.

Appellants scrutinize the references in the Examiner's allegation. The abstract of Chen describes synthesis of the saccharide monomers and formation of the hydrophilic, hydrophobic and thermoreversible gels and foams, but nothing on polylactic acid and polybutylene succinate.

In Chen, polymerizable saccharide monomers are made by the reaction of a saccharose and a (meth)acrylate. Hydrophilic, hydrophobic and thermoreversible gels and foams are formed upon polymerization of the saccharide monomers. Hydrophilic sucrose monomers are synthesized by reaction of sucrose with an epoxy acrylate. Hydrophobic sucrose monomers are synthesized by reaction of sucrose with methacrylol chloride followed by acetyl chloride. Thermoreversible sucrose monomers are obtained by modifying sucrose with polymerizable substituents prepared from methacryloyl chloride and aminocarboxylic acids. The modified sucrose monomers are copolymerized with hydrophobic poly(alkyleneoxide) (meth)acrylates to produce hydrogels exhibiting inverse thermoreversible properties. The thermosensitive hydrogels are biodegradable and can be used in the area of controlled drug delivery.

Column 6, line 35 of Chen merely suggests the possible Diels-Alder reaction of the conjugated diene structure in the saccharide monomer, formula (IV), but does not teach or suggest the Diels-Alder type functional groups with covalent bonds at lower than 100°C and splits at over 120°C.

In formula (IV), the terminal R_1 group is preferably a lower alkyl group. The conjugated diene structure of the monomer can be polymerized in the usual free radical manner, i.e., with one or both olefin groups being saturated upon polymerization. Alternatively, the diene can react with an olefin of another molecule in Diels-Alder fashion, with the remaining unreacted olefin group being polymerized.

Figures 1(A-G) of Chen show the synthesizing flows of the saccharide monomers, but nothing on polylactic acid and polybutylene succinate.

Figures 12(A-C) of Chen depict the thermoreversible swelling and shrinking of the sucrogels, which are attributed to the expansion and contraction of the sucrogels' polymer chains and cells, but nothing on the Diels-Alder type functional groups with covalent bonds at lower than 100°C and splits at over 120°C. The term "thermoreversible" means, in this context, relaxation and restriction of the polymer chain and cells, but not chemical bond and cleavage of the functional groups.

The thermoreversibility of swelling and shrinking of sucrogels were investigated by measuring the swelling ratio as a function of time at two different temperatures. When sucrogels previously equilibrated at 4°C were placed into the container maintained at 60°C, sucrogels underwent a volume decrease immediately (FIG.12, and also see column 25, lines 38-43 of Chen).

As shown in FIG.12, the swelling and shrinking profiles were reproduced in subsequent swelling-shrinking cycle (see column 25, lines 53-54 of Chen).

Example II-1 describes synthesis of the sucrose methacrylate acetate (S-MA-A) monomers, but nothing on polylactic acid, polybutylene succinate and the Diels-Alder type functional groups.

Two batches of S-MA-A monomers were synthesized following reaction (II) shown in FIG.1.

Example III-1 states synthesis of the N-methacryloyl aminocarboxylic acids, but nothing on polylactic acid, polybutylene succinate and the Diels-Alder type functional groups.

N-methacryloyl aminocaproic acid and N-methacryloyl leucine were synthesized according to previous methods with slight modification.

Example III-2 explains synthesis of the sucrose monomers by esterifications of sucrose, but nothing on polylactic acid, polybutylene succinate and the Diels-Alder type functional groups.

Esterifications of sucrose with N-methacryloyl aminocarboxylic acids were carried out using the Mitsunobu reaction. The general procedure of the reaction was adapted from a previous method with slight modification.

Accordingly the above references never come to the Examiner's conclusion that "Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120°C."

a2)

Ruben reveals a kit for providing a flexible intra-oral bandage capable of intra-oral adhesion and intra-oral drug delivery in a water-based system (see column 1, lines 8-12).

The kit comprises a hydrolyzable powder/water-wettable fiber mixture enclosed in a flexible, water-permeable, non-stick envelope. The hydrolyzable powder/water-wettable fiber mixture is composed of a polysaccharide powder, such as an alginate powder, mixed with water-wettable fibers, such as cellulose fibers (see column 4, lines 53-60, Figure 1A-G of Ruben), an example composition of which is as follows (see column 5, lines 48-53 of Ruben):

1. about 8 weight percent sodium or potassium alginate;
2. about 8 weight percent calcium sulfate;
3. about 47 weight percent diatomaceous earth;
4. about 1 weight percent tri-sodium phosphate;
5. about 1 weight percent corn starch; and
6. about 30 weight percent cotton fiber.

The bandage kit is immersed in water or another aqueous liquid, whose temperature is between 10°C and 25°C (see column 7, lines 34-42, Figure 1A-G of Ruben).

Once the bandage kit has been fully soaked with the liquid, the user removes the powder/water-wettable fiber mixture from the envelope, manually molds the powder/water-wettable fiber mixture to form the bandage of the desired shape, or folds the wetted tissue, places the wetted bandage in a desired location in his or her mouth, and secures the bandage to the desired location by applying light manual pressure to the gelled bandage, causing it to adhere to the tissue surface (see column 8, lines 14-26, Figure 1A-G of Ruben).

Appellants note that the biodegradable moldable resin of the present invention as recited in claim 43, could function as a durable plastic, whereas Ruben's hydrolyzable powder/water-wettable fiber mixture could be used for a drug delivery system, similar to Chen's foams and gels. The relevant technical fields are different. The present invention can not be moldable at temperatures lower than 100°C, whereas Ruben's hydrolyzable powder/water-wettable fiber mixture can. The combination of Ruben with Chen would never result in the present invention, which could be a hardwearing plastic at temperatures lower than 100°C, and could be moldable at temperatures over 120°C. Therefore, the Examiner's conclusion is incorrect.

a3)

Helmus teaches a prosthetic heart valve resistant to tissue overgrowth following the implantation of the prosthetic heart valve into a host. The prosthetic valves comprise a sewing ring, typically constructed of a fabric, and a housing component, the valve components within the housing component or a combination thereof comprise a biologically active material that prevents or reduces the tissue overgrowth (see page 2, paragraph 0016 of Helmus).

Any one, or all of these components are fabricated from a metal, pyrolytic carbon, a polymeric material, or a combination thereof. One or more of the various components of the valve (e.g., housing, leaflets, sewing ring, etc.) can also be coated with a polymeric material, a textile or a combination thereof (see page 2, paragraph 0024 of Helmus).

The bioactive agents can be incorporated into the devices using one or more of the many art-recognized techniques for immobilizing, or adhering, drug molecules to other molecules and surfaces. These methods include covalent or non-covalent attachment to the device of the drug (see page 3, paragraph 0036 through page 7, paragraph 0081 of Helmus).

The sewing ring, the housing component, the valve components within the housing and combinations thereof are at least partially covered with a coating for release of at least one biologically active material. The coating can be in the form of gels (e.g., hydrogel, thermoreversible gel), foams, suspensions, microcapsules, solid polymeric materials and fibrous or porous structures (see page 7, paragraph 0082 through page 10, paragraph 0121 of Helmus).

The biologically active material is incorporated into a polymeric component by encapsulation in a microcapsule (see page 10, paragraph 0122 through page 11, paragraph 0141 of Helmus).

Appellants note that the biodegradable moldable resin of the present invention as recited in claim 43, could provide a long-lasting plastic, whereas Helmus could unveil the incorporation of bioactive agents into a prosthetic heart valve to prevent or reduce the tissue overgrowth. The technical fields are distinct from each other.

Appellants look at the references in the Examiner's view. Page 6, paragraph 0068 of Helmus describes the covalent binding of the bioactive agent to a material that coats one or more components of the prosthetic valve. Paragraph 0068 only suggests that the attachment of the bioactive agent can be reversible through a cleavable linker, and polylactic acid can be one of the coating materials. Paragraph 0068 implies nothing on the resin prepared from polylactic acid nor on the thermally reversible cross-linked structure.

In regards to paragraph 0068, in another preferred embodiment, the bioactive agent is covalently bound to a material that coats one or more components of the prosthetic valve of the invention. The discussion above regarding functionalizing of polymers is generally relevant to embodiments in which the bioactive agent is covalently attached to one or more components of a species coating the prosthetic valve. The agent can be attached to the coating in a manner that is

either reversible (e.g., through a cleavable linker) or irreversible. Exemplary coatings to which the bioactive agent can be attached include, for example, synthetic polymers (e.g., poly(urethanes), poly(acrylamides), etc.), "natural" polymers (e.g., polylactic acid, polyglycolic acid, polyamino acid, etc.), hydrogels, thermoreversible gels, pluronics, fibrin sealants, and the like. Methods for preparing monomers functionalized with a particular bioactive agent, and for functionalizing polymeric materials with a bioactive agent are well known and accessible to those of skill in the art.

Paragraph 0122 of Helmus discloses the incorporation of the bioactive material into the polymeric component by encapsulation, but nothing on the resin prepared from polylactic acid nor on the thermally reversible cross-linked structure.

In regards to paragraph 0123 of Helmus, in another preferred embodiment, the biologically active material is incorporated into a polymeric component by encapsulation in a microcapsule. The microcapsule is preferably fabricated from a material different from that of the polymeric component and the bulk of the coating matrix.

Paargraph 0130 of Helmus explains the method fabricating the microparticles with the bioactive agent, but nothing on the resin prepared from polylactic acid nor on the thermally reversible cross-linked structure.

In regards to paragraph 0131, in this method, the polymer is first melted and then mixed with the solid particles of biologically active material that have preferably been sieved to less than 50 microns. The mixture is suspended in a non-miscible solvent (like silicon oil) and, with continuous stirring, heated to about 5°C above the melting point of the polymer. Once the emulsion is stabilized, it is cooled until the polymer particles solidify. The resulting microparticles are washed by decantation with a solvent such as petroleum ether to give a free-

flowing powder. Microparticles with sizes ranging from about 1 to about 100 microns are obtained with this method. The external surfaces of capsules prepared with this technique are usually smooth and dense. This procedure is preferably used to prepare microparticles made of polyesters and polyanhydrides.

Paragraph 0114 of Helmus exemplifies the hydrogels which are crosslinked block copolymers having a water-soluble central block segment sandwiched between two hydrolytically labile extensions. The water soluble central block can include poly(ethylene glycol); the hydrolytically labile extensions can be a polylactic acid. Line 0114 gives no hint on the resin prepared from polylactic acid nor on the thermally reversible cross-linked structure, for the hydrogels have the same structural changes as Chen's foams and gels.

In regards to paragraph 0114 of Helmus, biocompatible hydrogel compositions whose integrity can be controlled through crosslinking are known and are presently preferred for use in the prosthetic valves of the invention. For example, Hubbell et al., U.S. Pat. No. 5,410,016, which issued on Apr. 25, 1995 and U.S. Pat. No. 5,529,914, which issued on Jun. 25, 1996, disclose water soluble systems, which are crosslinked block copolymers having a water-soluble central block segment sandwiched between two hydrolytically labile extensions. Such copolymers are further end-capped with photopolymerizable aerylate functionalities. When crosslinked, these systems become hydrogels. The water soluble central block of such copolymers can include poly(ethylene glycol); whereas, the hydrolytically labile extensions can be a poly(a-hydroxy acid), such as polyglycolic acid or polylactic acid. See, Sawhney et al., Macromolecules 26: 581-587 (1993).

Paragraph 0116 of Helmus teaches another gel example, the thermoreversible gel, which would never come to the resin prepared from polylactic acid nor the thermally reversible cross-linked structure, since the thermoreversible gel works similarly to Chen's foams and gels.

In regards to paragraph 0116 of Helmus, in another preferred embodiment, the gel is a thermoreversible gel. Thermoreversible gels including components, such as pluronics, collagen, gelatin, hyalouronic acid, polysaccharides, polyurethane hydrogel, polyurethaneurea hydrogel and combinations thereof are presently preferred.

Under the foregoing examination, it is unquestionable that the references never bring about the Examiner's assertion, "It would have been obvious to a person of ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material are known material based on its suitability for its intended use." Therefore, this rejection is without merit and should be overruled.

b. Dependent claims 44, 51-54 and 131

Dependent claims 44, 51-54 and 131 depend from independent claim 43 and further define the claimed invention. Specifically, claim 44 recites, "*wherein said Diels-Alder type functional group is at least one group selected from the group consisting of an alkenyl group and group having a conjugated double bond.*" This feature is not taught or suggested by the cited references.

Further, claim 51 recites, "*wherein said biodegradable moldable resin has a three-dimensional cross-linked structure, and the cross-linked density of the three-dimensional cross-linked structure is 0.0001 to 1.*" This feature is not taught or suggested by the cited references.

Further, claim 52 recites, "*wherein the main chain of said biodegradable moldable resin has at least one of a linear structure and branched structure.*" This feature is not taught or suggested by the cited references.

Further, claim 53 recites, "*wherein one or more of said functional groups are present at the same site, at least one of the end and side chain of said biodegradable resin.*" This feature is not taught or suggested by the cited references.

Further, claim 54 recites, "*wherein an electrostatically bondable and thermo-reversible cross-linked structure is used together.*" This feature is not taught or suggested by the cited references.

Further, claim 131 recites, "w*herein the functional group is selected from the group consisting of cyclic dienes and cyclic dienophiles.*" This feature is not taught or suggested by the cited references.

Therefore, dependent claims 44, 51-54 and 131 all include at least one element, which is not taught or suggested by the alleged combination of references.

b1)

Furthermore, regarding claim 131, Wiessler discloses a method of synthesizing saccharide compounds comprising the steps of:

a. attaching at least one saccharide to a cyclic or acyclic diene,

b. reacting the saccharide-containing diene with a dienophile by Diels-Alder reaction (see column 1, lines 43-49).

Step a comprises the synthesis of the polyhydroxylated furan derivatives which permit the covalent, glycosidic linkage with a saccharide molecule (see column 6, lines 5-23, Figure

5(a)-(f) of Wiessler), and the glycosidation of the polyhydroxylated furan (see column 6, lines 24-39, Figure 6 of Wiessler).

Step b is the Diels-Alder reaction of the furan glycoside with the N-substituted malainimides, providing a variety of saccharides (see column 6, line 40 through column 8, line 20, Figure 2-3 of Wiessler).

Appellants note that the object of the present invention is to provide an industrial-strength plastic, whereas that of Wiessler is to give saccharide libraries and saccharide-containing compound libraries, which are suited as therapeutic agents, interacting with receptors in/on cells or organs (see column 1, lines 29-34 of Wiessler). The target technical fields are different. The present invention is prepared from polylactic acid or polybutylene succinate, whereas Wiessler's libraries are saccharide conjugates and mimetics. When the primary polymers are different, so are the chemistries; the present invention experimentally manifests the data on cleaving temperature, heat resistance, biodegradability, recycling property, molding property and wet resistance (see table 2 in the present application); Wiessler only teaches the method synthesizing the saccharide and saccharide mimetics libraries, and fails to suggest this data. Further, it is conceivable that the cleaving temperature depends on the functional groups introduced into the resin (see Specification page 26, lines 9-27 of Wiessler). Thus, the combination of Chen, Ruben, Helmus and Wiessler would never lead to the present invention. Therefore, this rejection is without merit and should be overruled.

(c) Conclusion

Based on the above arguments, Appellants respectfully submit that claims 43, 44, 51-54 and 131 are non-obvious under 35 U.S.C. § 103(a) in light of the cited references. Therefore, the rejections of the claims based on 35 USC § 103(a) and the references are in error. In view of the remarks submitted hereinabove, the references applied against Claims 43, 44, 51-54 and 131 on appeal do not render the claims unpatentable under 35 U.S.C. § 103(a). Thus, Appellants submit that the rejections under 35 U.S.C. § 103(a) are in error and must be reversed.

Should any fees be required, authorization is hereby given to charge deposit account 19-1013.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

43. (Rejected) A biodegradable moldable resin having a Diels-Alder type functional group having a thermo-reversible cross-linked structure which is covalently bonded by cooling and cleaved by heating,

wherein said functional group forms said thermo-reversible cross-linked structure which is covalently bonded at a temperature for use as a molded article and cleaved at temperatures over 120°C and equal to or lower than the molding temperature, and wherein said Diels-Alder type functional group forms the covalent bonds,

wherein the biodegradable resin is selected from the group consisting of polylactic acid, modified body of the polylactic acid, polybutylene succinate and modified body of the polybutylene succinate.

44. (Rejected) The biodegradable resin according to claim 43, wherein said Diels-Alder type functional group is at least one group selected from the group consisting of a alkenyl group and group having a conjugated double bond.

51. (Rejected) The biodegradable moldable resin according to claim 43, wherein said biodegradable moldable resin has a three-dimensional cross-linked structure, and the cross-linked density of the three-dimensional cross-linked structure is 0.0001 to 1.

52. (Rejected) The biodegradable moldable resin according to claim 43, wherein the main chain of said biodegradable moldable resin has at least one of a linear structure and branched structure.

53. (Rejected) The biodegradable moldable resin according to claim 43, wherein one or more of said functional groups are present at the same site, at least one of the end and side chain of said biodegradable resin.

54. (Rejected) The biodegradable moldable resin according to claim 43, wherein an electrostatically bondable and thermo-reversible cross-linked structure is used together.

131. (Rejected) The biodegradable moldable resin according to claim 43, wherein the functional group is selected from the group consisting of cyclic dienes and cyclic dienophiles.

IX. EVIDENCE APPENDIX

Not applicable.

X. RELATED PROCEEDINGS APPENDIX

Not applicable.